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Please find below and/or attached an Office communication concerning this application or proceeding.



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JAN 22 2004

HAMILTON, BROOK, SMITH AND REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD MA 01742-9133

In re Application of

GILCHREST et al

Serial No.: 09/632,748

: Decision on Petition

Filing Date: 4 AUGUST 2000

Attorney Docket No 0054.1087-010

This letter is in response to the Petition filed under 37 CFR 1.144, to withdraw the restriction requirement, filed with a certificate of mailing date of 15 September 2003. The delay in acting on this petition is regretted.

BACKGROUND

A review of the file history shows that the application was filed on 4 August 2000 under 35 USC 111(a).

In Paper No. 9, mailed 21 June 2002, the Office restricted the 32 claims into ten patentably distinct groups. Since the groupings within the restriction requirement are not part of the petition, they will not be discussed further. The Examiner also set forth an election of species as summarized below:

- (a) peptide comprising KGK
- (b) peptide comprising KGA
- (c) SEQ ID No. 4
- (d) SEQ ID No. 9 or
- (e) SEQ ID No. 10.

The restriction requirement failed to give any reasons why species (a)-(e) were patentably distinct. Applicants elected Group VII, original claims 10 (in part), 11 and 12 and the species "peptide comprising KGA."

In the first Office action on the merits, mailed 19 November 2002, the examiner conceded that the traversal was partially persuasive. The Examiner indicated that new Group II (perhaps the Examiner had intended to say Group VII?) claims 10-11 and 14-15 and the peptide sequence KGA would be examined. From the Office action, it is not clear how linking claims 10, and 14, which are found in both groups VI and VII and VIII and IX, were divided. The Office action is unclear with regard to which groups were rejoined. Claims 1-9, 12-13 and 16-32 were withdrawn from further consideration, citing 37 CFR 1.142(b), as being drawn to non-elected invention.

The response filed 23 April 2003 amended claims 10 and 14 and added new claims 33-38.

On 14 July 2003, the Office mailed a final action, in which Claims 10, 14, 33-34 and 36-37 were examined and rejected under 35 USC 102(b) as being anticipated by Reams. Claims 1-9, 12-13, 16-32, 35 and 38 were withdrawn from consideration. The examiner reasoned that claims 35 and 38 were directed to independent and distinct inventions because none of the sequences were elected as the species to be examined in Paper No. 11, filed 8/30/02. Applicants were advised that if they wished to have claims narrower in scope searched and examined, they may file a divisional application.

Applicants filed remarks and this petition on 22 September 2003.

An advisory action was mailed 24 December 2003.

DISCUSSION

The application, file history and petition have been considered carefully.

The petition requests that claims 35 and 38 be examined together with the elected invention.

Independent claim 10, dependent claim 34, reciting elected species, peptide comprising KGA (lysine-glycine-alanine), and new claim 35, withdrawn as being directed to non-elected invention, are presented below.

10. (Amended) A method of maintaining or inducing hair color in a mammal, said method comprising inhibiting p75 nerve growth factor receptor-mediated apoptosis in epidermal melanocytes wherein the apoptosis is inhibited by contacting the melanocytes with a neurotrophin or a biologically active fragment

thereof that binds to the p75 nerve growth factor receptor expressed on melanocytes.

34. (New) The method of Claim 10 wherein the biologically active fragment is a peptide comprising amino acid sequence lysine-glycine-alanine.

35. (New) The method of Claim 34 wherein the peptide consists of SEQ ID NO:4, SEQ ID NO:9 or SEQ ID NO:10.

Claims 14, 37 and 38 follow a similar format.

It is noted that claim 35 is narrower in scope from and properly depends from claim 34, reciting the elected species. Moreover, new claim 38 is narrower in scope from and properly dependent upon claim 14.

The petition states that amino acid sequences of SEQ ID Nos. 4, 9 and 10 are as follows:

SEO ID NO:4 - CVGSNKGAIC

SEQ ID NO:9 - CATDIKGAEC

SEQ ID NO:10 - CKGAIC

As highlighted in bold, above, each of the sequences contain the elected "species" KGA (lysine-glycine-alanine). The remaining sequences surrounding the shared trimer KGA are not significantly similar.

The Restriction Requirement invited applicants to elect a species from a group that included a genus of molecules, those comprising KGA or KGK, and then three species, which fall into the scope of peptides comprising KGA. As such, the species requirement was incorrect. Once it had become apparent the elected "species" encompasses some of the other species, reconsideration of the species election is in order, since the Office has not defined patentably distinct subject matter.

The Examiner was incorrect in withdrawing claims 35 and 38 from examination. If SEQ ID Nos. 4, 9 and 10 represent patentably distinct inventions, (and this determination has yet to be properly made in this application) then claims 10, 14, 34 and 37 with the election of the species "peptide comprising KGA" are linking claims and should be treated as such. MPEP 809 provides guidance on treatment of linking claims.

MPEP 809 states that

Where, upon examination of an application containing claims to distinct inventions, linking claims are found, restriction can nevertheless be required. See MPEP § 809.03 for definition of linking claims. A letter including only a restriction requirement or a telephoned requirement to restrict (the latter being encouraged) will be effected, specifying which claims are considered linking. See MPEP § 812.01 for telephone practice in restriction requirements. No art will be indicated for this type of linking claim and no rejection of these claims made.

A 1-month (not less than 30 days) shortened statutory period will be set for reply to a written requirement. Such action will not be an "action on the merits" for the purpose of the second action final program. To be complete, a reply to a requirement made according to this section need only include a proper election. The linking claims must be examined with the invention elected, and should any linking claim be allowed, the restriction requirement must be withdrawn. Any claim(s) directed to the nonelected invention(s), previously withdrawn from consideration, which depends from or includes all the limitations of the allowable linking claim must be rejoined and will be fully examined for patentability. Where such withdrawn claims have been canceled by applicant pursuant to the restriction requirement, upon the allowance of the linking claim(s), the examiner must notify applicant that any canceled, nonelected claim(s) which depends from or includes all the limitations of the allowable linking claim may be reinstated by submitting the claim(s) in an amendment. Upon entry of the amendment, the amended claim(s) will be fully examined for patentability.

If the peptides of SEQ ID No 4, 9 and 10 represent patentably distinct inventions, then the Examiner needs to inform applicants of such and allow them to chose which of the three sequences they wish to have examined along with the elected invention. Should the linking claim become allowable, then the species need to be rejoined for examination.

DECISION

The petition is **GRANTED-IN-PART** for the reasons set forth above.

The finality of the Office action has been withdrawn. The restriction between Species (b), peptide comprising KGA, and Species (c), SEQ ID No. 4, Species (d) SEQ ID No. 9 and Species (e) SEQ ID No. 10 has been withdrawn because each of SEQ ID No. 4, 9 and 10 are peptides comprising KGA.

The application is being forwarded to the Examiner for action consistent with this petition decision.

If claims reciting Species (b) are not in condition for allowance, the Examiner may set forth an election of species among Species (c), SEQ ID No. 4, Species (d) SEQ ID No. 9 and Species (e) SEQ ID No. 10 to allow applicants the opportunity to chose which of the three SEQ ID Nos. they want to have considered first. This election of species should properly explain why the species are independent and patentably distinct and why it would be a unduly burdensome to search the three sequences together with elected Species (b), peptide comprising KGA.

Should claims reciting Species (b) become allowable, then all dependent claims reciting SEQ ID Nos. 4, 9 and 10 should be rejoined for examination.

The Examiner is also requested to clarify which groups were rejoined in response to the election and traversal.

Should there be any questions with regard to this letter, please contact Special Program Examiner Julie Burke by letter addressed to the Director, Technology Center 1600, P.O. Box 1450, Alexandria VA, 22313-1450 or by telephone at (703) 308-7553 or by facsimile transmission at (703) 308-7230.

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